Device Interventions for Stroke Prevention in Atrial Fibrillation

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Atrial fibrillation (AF) is the most common sustained heart rhythm disorder, with an estimated prevalence of 0.4% to 1% in the general population. In addition, AF is responsible for approximately 15% to 20% of ischemic strokes. Device interventions to prevent strokes in patients with AF are nonsurgical procedures to block blood clots (thrombus) from forming and traveling out of the heart. The “quivering” rather than normal contractions of the upper chambers of the heart (atria) from disorganized electric activity (AF) leads to blood stasis and thrombus formation. A small cul-de-sac called the left atrial appendage (LAA) is especially prone to thrombus formation (Figure 1). In AF patients without valvular heart disease, almost all thrombus originates from the LAA. The thrombus travels to and block major vessels in the body. Blocking blood vessels to the brain leads to strokes and transient ischemic attacks (mini-strokes).

Patients with the following risk factors have a higher stroke risk: heart failure, hypertension, age of 75 years or greater, diabetes mellitus, and prior history of strokes or mini-strokes. These are often combined to form the CHADS₂ score. The more risk factors you have, the higher your CHADS₂ score and risk of stroke are.

Blood-thinning medications (anticoagulants) such as warfarin, dabigatran, rivaroxaban, and apixaban are effective stroke prevention therapies. The risks of bleeding associated with long-term anticoagulation led to the development of permanent treatment options like surgery. Closures by sutures (ligation) and removal (amputation) of the LAA are common surgical techniques. However, studies have shown that most closures were incomplete.

Newer nonsurgical interventions deploy closure devices to block the LAA. The procedure is nonsurgical because it is performed with small sterile tubes (catheters) through a vessel in the groin (percutaneous). Compared with surgery, patients have a much shorter recovery time and hospital stay. Closure devices can be placed inside (endocardial) or around (epicardial) the LAA.

What Devices Are Available?
The WATCHMAN device (Atritech, a subsidiary of Boston Scientific, Plymouth, MN) is a self-expanding endocardial device made from nitinol (nickel-titanium alloy; Figure 2A). The top of the device is covered with a permeable polyester fabric that acts like a filter initially and within a month becomes covered by the patient’s own cells. Stabilizing wires on the device keep it in place.

The AMPLATZER Amulet (AGA, St. Jude Medical, Minneapolis, MN) is another self-expanding endocardial device made from nitinol (Figure 2B). It has a lobe and a disk connected by a waist. A polyester material is sewn into both parts, and stabilizing wires keep it in place.

The third (and to date the last) available device is the LARIAT (SentreHEART, Inc, Palo Alto, CA), an epicardial device designed to deliver a snare remotely (Figure 2C). The snare is made from a nonabsorbable polyester suture and closes the LAA when it is tightened.

Of the 3 devices, the WATCHMAN device is the most studied. Compared with warfarin, the WATCHMAN device has demonstrated similar reductions in stroke risk and much improved long-term survival.¹

Am I Eligible for a Device?
If you are in the United States, the WATCHMAN and AMPLATZER Amulet are currently available for investigational use only. Briefly, to be eligible, you must be able to take an anticoagulant and have at least 1 risk factor for stroke. Outside the United States, use of the 2 devices is less restricted.

The LARIAT is available in the United States and Europe but does not carry a specific indication for stroke prevention in nonvalvular AF. Patients unable to take anticoagulants can get this device. However, patients with previous heart surgery and large, complex LAA are not suitable because of the design of the LARIAT.

The above information is correct at the time of publication. As devices and indications update over time, your cardiologist will be able to keep you up to date with any developments. At the time of publication, the WATCHMAN and AMPLATZER Amulet LAA closure devices are not available for sale in the United States.

What to Expect Before the Procedure
Your cardiologist will see you 2 to 3 weeks beforehand to discuss the procedure with you in more detail. A standard set of tests will be checked, including physical examination, blood test, clotting time (international normalized ratio), and transesophageal echocardiogram, a heart ultrasound via a small imaging probe down your esophagus (swallowing tube). A computed tomography scan of the heart is needed for the LARIAT. If you are on warfarin, it will be stopped 4 days before the procedure and replaced with enoxaparin shots (injections).

What to Expect the Day of the Procedure
You will need to fast for 8 hours before the procedure. The procedure will take place in the cardiac catheterization laboratory with medications to make you relaxed and sleepy (conscious sedation) or fully asleep (general anesthesia). A transesophageal echocardiogram is repeated to check for LAA thrombus (if found, the procedure will be stopped), to check the LAA size (to select the size of the endocardial device), and to assist in the procedure. X-rays and contrast (a liquid that shows up on x-rays) will be used in the procedure. Through the percutaneous access, a small puncture is made between the atria for the LAA delivery catheter (Figure 2D). The position and stability of the deployed endocardial device are checked before all catheters are removed. The procedure takes about 1 to 2 hours, and you will remain in hospital overnight for observation.

The LARIAT requires an additional access below your chest and into the sac around the heart (pericardium). Through this, the LARIAT goes around the LAA, and after it is tightened and deployed, it is replaced with a small drain that is removed the next day (Figure 2E and 2F). No device is
deployed within the LAA. You will need to remain in the hospital over the next 1 to 2 nights.

**Procedure Risks**
Access-related bruising in the groin and chest discomfort (pericardial inflammation following the LARIAT) are the commonest procedural risks. Uncommon risks include an unsuccessful procedure resulting from an inability to deploy a device, allergic reactions to medications and contrast, and thrombus forming on the device. Rare (less than 1%) risks include strokes during the procedure, accumulation of fluid around the heart requiring immediate drainage, device migration or dislodgement, infection, heart attack, and death. Patients with severe nickel allergy may need to avoid the endocardial devices.

**What to Expect After the Procedure**
Before you are discharged, your cardiologist will examine you, and an echocardiogram with a chest probe (transthoracic echocardiogram) will be performed. Anticoagulation will be restarted, and antibiotics maybe required in the next 6 months to prevent bacterial infections, especially if you have procedures like dental cleaning. A series of follow-up visits are required, the first at 45 days. A transesophageal echocardiogram is required then and again later to check how well the LAA is closed. If the LAA is not closed (more than a 5-mm gap), anticoagulation is continued; otherwise, it is stopped indefinitely. Without the potential bleeding that is associated with long-term anticoagulation, your prognosis is as good as if not better than that of anticoagulated patients.

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**References**

**Additional Resources**
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